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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,006	06/29/2001	Gregory T. Bleck	GALA-06415	1148

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EXAMINER
MARVICH, MARIA

ART UNIT	PAPER NUMBER
1636	10

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/897,006	Applicant(s) BLECK, GREGORY T.	
	Examiner Maria B Marvich, PhD	Art Unit 1636	

-- The MAILING DATE of this communication app ars on th cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 17, 19 and 20 are drawn to nucleic acid, vectors, host cells and methods of use related to SEQ ID 1, classified in class 536, subclass 23.1 and 23.5 and class 435,subclass 69.1, 440 and 325.

II. Claims 5-11 and 18 are drawn to nucleic acid, vectors and host cells and method of using related to SEQ ID 2, classified in class 536, subclass 23.1 and 23.5 and class 435,subclass 69.1, 440 and 325.

III. Claims 12-16 are drawn to nucleic acid, vector and host cells encoding IRES and signal peptides classified in class 536, subclass 23.1 and 23.5 and class 435,subclass 69.1, 440 and 325.

IV. Claims 21-29 and 31-33 is drawn to a method of producing an immunoglobin classified in class 530, subclass 350.

V. Claim 30 is drawn to an antibody classified in class 424, subclass 130.1.

Inventions are distinct, each from the other because of the following reasons.

Group I and II and III read on patentably distinct DNA sequences from distinct genes. Each DNA sequence is patentably distinct because they are unrelated sequences. For each of Groups I-III applicants must elect a single nucleic acid sequence (i.e. SEQ ID NO) for examination. See MPEP 803.04 which states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally

constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, select to a restriction requirements pursuant to 35 U.S.C. 1121 and CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry to protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

It has been decided that, due to the high burden placed on the Office to search sequences, ONE sequence constitutes a reasonable number for examination purposes. Applicant is required to elect ONE independent and distinct sequence. Examination will be restricted to only the one elected sequence. The search of no more than one selected sequences may include the complements of the selected sequence and where appropriate, may include subsequences within the selected sequence (i.e. oligomeric probes and/or primers).

The inventions of Groups I-III and Groups IV-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP 806.04, 808.01). In the instant case, the inventions are drawn to chemically distinct entities. For example, the nucleic acids of groups I-III are chemically and structurally distinct from the antibody of group V. The methods of group IV and of groups I-II are unrelated because the methods involve distinct unrelated method steps and have different effects (e.g. group IV is drawn to a method of producing an immunoglobin while group I-II are drawn to methods of use of SEQ ID 1 and 2). The nucleic acids of group III are separate and distinct from the methods of group IV wherein the nucleic acids may neither be made by, nor used, in the methods of Group IV.

Inventions IV and V are related as product and process of making. The inventions are distinct if either or both of the following can be shown (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case, the product as claimed may be produced synthetically or may be produced in an animal in response to antigen introduction.

The searches required for group I (SEQ ID NO: 1, hybrid human-bovine alpha lactalbumin promoter) and II (SEQ ID NO: 2 or a mutant RNA export element and III (IRES-signal peptide sequence) read on patentably distinct and unrelated sequences. Art pertaining to each group is separate and distinct and require non-coextensive searches. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter or different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon cancellation of claims to a non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kay Pinkney, whose telephone number is (703) 305-3553.

Maria B Marvich, PhD
Examiner
Art Unit 1636

PATENT EXAMINER

November 17, 2002